Paper No. 19

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JAMES U. MORRISON

Appeal No. 2004-1112
Application No. 09/829,707

ON BRIEF

Before SCHEINER, MILLS, and GRIMES, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 15-27 and 43. Claims 1-14 and 28-42 are also pending but have been withdrawn from consideration. Claims 15 and 43 are representative of the subject matter on appeal and read as follows:

15. A chemical composition used to stimulate weight loss in a patient, comprising:

acarbose; and

a sustained release matrix,

wherein said acarbose and sustained release matrix are combined to form a mixture.

43. A method of treating a patient to stimulate weight loss comprising administering an acarbose formulation to the patient, wherein such formulation does not include a lipase inhibitor.

The examiner relies on the following references:

Bremer et al. (Bremer)	5,643,874	Jul. 1, 1997
Patel et al. (Patel)	6,309,663	Oct. 30, 2001
Rosner	6,387,361	May 14, 2002

Claim 43 stands rejected under 35 U.S.C. § 102(a) as anticipated by Rosner. Claims 15-27 stand rejected under 35 U.S.C. § 102(b) as anticipated by Bremer, and under 35 U.S.C. § 102(e) as anticipated by Patel.

We reverse all of the examiner's rejections and enter a new rejection of claim 43.

Background

"Acarbose is an oral alpha-glucoside [sic, glucosidase?] inhibitor approved for use in the management of non-insulin-dependent diabetes mellitus (NIDDM). Acarbose is [a] complex oligosaccharide that delays the digestion of ingested carbohydrates." Specification, page 4. "Acarbose . . . is marketed as an orally administered drug under the name Precose® and Glucobay®. Both Precose® and Glucobay® are simply coated with a delayed release coating." Id., page 1.

The specification discloses that "[s]ustained release products are widely recognized in the art and are of extreme importance in the pharmaceutical field." Id., page 2. Such products are recognized as "provid[ing] a stable, predetermined concentration of a drug in the small intestine, without requiring close monitoring and frequent re-administration. See id., page 3. One common

method of achieving sustained release is to "provide[e] a sustained release matrix, such as a fat, a wax, or a polymeric material intermixed with the active ingredient in the tablet itself." Id.

The specification discloses "a composition comprised of acarbose and a sustained release polymeric matrix . . . [and] a method of treating a patient to stimulate weight loss, such method comprised of administering an acarbose formulation to the patient. The acarbose formulation may be mixed with a delayed release matrix, or alternatively may be mixed with a sustained release matrix." Id. The specification "propose[s] that constant levels of acarbose . . . will produce constant inhibitory activity against the digestion of oligosaccharides, thus inhibiting the production of simple sugars. If the utilization of carbohydrates is inhibited, body fat will be used for energy, thus producing weight reduction." Page 5. The specification provides a working example of weight loss produced by acarbose administration in combination with a diet-and-exercise regimen. See page 10.

Discussion

The claims stand or fall together with respect to each rejection. See the Appeal Brief, page 3. Thus, claims 16-27 will stand or fall with claim 15. Claims 43 stands or falls separately. Claim 15 is directed to a composition consisting essentially of a mixture of acarbose and a sustained release matrix. Claim 43 is directed to a method of stimulating weight loss comprising administering "an acarbose formulation to the patient, wherein such formulation does not include a lipase inhibitor."

The examiner rejected claim 43 as anticipated by Rosner, and rejected claims 15-27 as anticipated by either Bremer or Patel.

1. Rosner

The examiner rejected claim 43 "under 35 U.S.C. 102(a) as being anticipated by Rosner," reasoning that Rosner "discloses a method of controlling weight in a human comprising administering to the human acarbose at meals with food containing carbohydrate, which anticipates the method of instant Claim 43." Examiner's Answer, pages 5 and 6.

Appellant argues that Rosner is not prior art under 35 U.S.C. § 102(a), because it issued on May 14, 2002, after the filing date of the present application. See the Appeal Brief, pages 3-4.[1] The examiner's response is that "the invention of the Rosner patent was known or used by others in this country before the filing date of the instant application, as suggested by the filing date of the Rosner patent dated August 2, 1999." Examiner's Answer, page 6.

We agree with Appellant that Rosner is not available as prior art under 35 U.S.C. § 102(a). "The statutory language, 'known or used by others in this country' (35 U.S.C. § 102(a)), means knowledge or use which is accessible to the public." Carella v. Starlight Archery, 804 F.2d 135, 139, 231 USPQ 644, 646 (Fed. Cir. 1986). As Appellant points out, Rosner was not accessible to the public, and therefore not available as prior art under 35 U.S.C. § 102(a), until it issued as a patent.

[1] Appellant also argues that Rosner does not anticipate because it does not disclose an acarbose "formulation", as that term is defined in the specification. This argument is addressed below to the extent that it is relevant to the new ground of rejection entered in this opinion.

Since Rosner did not issue until after the filing date of the instant application, it does not qualify as prior art under § 102(a). The correct statute for applying a patent that was filed before, but issued after, an application's filing date is 35 U.S.C. § 102(e). See In re Lund, 376 F.2d 982, 988, 153 USPQ 625, 630 (CCPA 1967) ("It is, of course, incontrovertible that a description of an invention of another in an application filed before an applicant's date of invention, upon which application a patent is issued, constitutes a bar to the issuance of a valid patent for the same invention, Alexander Milburn Co. v. Davis-Bournonville Co., 270 U.S. 390, 46 S.Ct. 324, 70 L.Ed. 651 (1926), codified by § 102(e)."). See also id. at 992 n.12, 153 USPQ at 633 n.12 ("Inasmuch as § 102(e) makes a description in a patent available as evidence of prior knowledge as of the effective filing date of the application on which the patent issues, it should be regarded as an exception to the general rule that prior knowledge must be public in order to defeat another's patent rights.").

2. Bremer

The examiner rejected claims 15-27 as anticipated by Bremer, on the basis that Bremer "discloses glucosidase and/or amylase inhibitors that can be manufactured as pharmaceutical compositions for the combined use with a lipase inhibitor." Examiner's Answer, pages 4-5. The examiner pointed to Bremer's suggestion of acarbose as one of the inhibitors that can be included in the disclosed compositions, and concluded that the "pharmaceutical composition that can be used to treat obesity of the Bremer et al[.] patent anticipates the

instantly claimed chemical composition used to stimulate weight loss in a patient." Id., page 5.

Appellant argues that the use of the transitional phrase "consisting essentially of" excludes compositions (such as Bremer's) that include a lipase inhibitor along with acarbose. Appeal Brief, pages 10-11. In response, the examiner argues that the addition of a lipase inhibitor to an acarbose-containing composition would not change the "basic and novel characteristics" of the composition, because "there is no indication in the Bremer et al[.] patent that the presence of the lipase inhibitor in the composition of the Bremer et al[.] patent alters the chemical formula of the acarbose and the hydroxypropylmethylcellulose of the Bremer et al[.] patent," and "Appellant has not clearly defined the 'basic and novel characteristics of the instantly claimed composition' in such a way that a lipase would be excluded from the instantly claimed composition." Examiner's Answer, pages 8 and 9.

We agree with Appellant that the instant claims do not read on the composition disclosed by Bremer. "By using the term 'consisting essentially of,' the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention." PPG Indus. Inc. v. Guardian Indus. Corp, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998).

The question, then, is: what are the basic and novel characteristics of the claimed composition? According to the specification, "[a]carbose is an inhibitor of the saccharase enzyme complex," which "delays the digestion of ingested

carbohydrates." Pages 1 and 4. The other required component of the claimed composition, a sustained release matrix, is disclosed to "provide[] substantially constant release of acarbose over a pre-determined period of time." Page 2. Thus, the basic and novel characteristics of the claimed composition are (1) inhibition of the saccharase enzyme complex, (2) over an extended period of time.

The basic and novel characteristics of the claimed composition do not include inhibition of lipase enzymes. Thus, the addition of a lipase inhibitor would materially affect the basic and novel characteristics of the claimed composition. The claims do not read on the compositions disclosed by Bremer, which all contain a lipase inhibitor. The rejection under 35 U.S.C. § 102(b) is reversed.

3. Patel

The examiner rejected claims 15-27 as anticipated by Patel, on the basis that Patel

> discloses a pharmaceutical composition that comprises surfactants and a hydrophilic therapeutic agent (see abstract), whereby the hydrophilic therapeutic agent may be selected as acarbose (see column 31, lines 57 and 58). Patel . . . discloses that the pharmaceutical compositions may be in dosage forms, whereby the dosage forms can be designed for extended release, which can be [e]ffected by a coated matrix composition. . . . [E]xamples of cellulose derivatives that can be used to form the coating composition . . . [include] hydroxypropyl methyl cellulose succinate.

Examiner's Answer, page 3.

Appellant argues that Patel does not anticipate claims 15-27 because, among other things, Patel does not disclose a formulation combining acarbose and a sustained-release matrix. Rather, Appellant argues, Patel discloses unit

dosages (e.g., tablets) coated with an extended-release coating. See the Appeal Brief, pages 7-9. Appellant argues that a coating changes the location of release of the active agent (from stomach to lower gastrointestinal tract) but does not provide a steady release of acarbose over an extended period of time, as a sustained-release matrix does. See id., page 8.

We agree with Appellant. Anticipation under 35 U.S.C. § 102 requires identical disclosure of the claimed invention in the prior art. See Gechter v. Davidson, 116 F.3d 1454, 1457, 43 USPQ2d 1030, 1032 (Fed. Cir. 1997) ("Under 35 U.S.C. § 102, every limitation of a claim must identically appear in a single prior art reference for it to anticipate the claim."); Richardson v. Suzuki Motor Co., Ltd., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) ("Every element of the claimed invention must be literally present, arranged as in the claim.").

The instant claims are directed to a mixture consisting essentially of acarbose and a sustained release matrix. See claim 15. The specification clearly distinguishes between a sustained release coating and a sustained release matrix:

> Sustained release is achieved by a variety of methods. Two common methods are: 1) providing a sustained release coating upon tablets or microspheres wherein slow release of the active ingredient occurs via either gradual permeation through or gradual breakdown of this coating; or 2) providing a sustained release matrix, such as a fat, a wax, or a polymeric material intermixed with the active ingredient in the tablet itself.

See page 3, lines 20-24 (emphasis added).

The claim limitations requiring the presence of a sustained release matrix, which must be mixed with the acarbose, shows that the claims are limited to

acarbose formulations made according to the second method described in the specification. According to the examiner, however, Patel discloses only "dosage forms [that] can be designed for extended release, which can be [e]ffected by a coated matrix composition." Examiner's Answer, page 3 (emphasis added). Thus, the claims do not read on the compositions disclosed by Patel.

We also note that the examiner has not pointed to any specific composition disclosed by Patel that contains both of the ingredients required by instant claim 15. Rather, the examiner pointed to a passage in Patel that disclosed acarbose as one of numerous possible active agents that could be used, and pointed to another passage in Patel teaching that the disclosed formulations could be made into coated dosages. The amount of picking-and-choosing needed to distill the claimed composition from the reference disclosure seems incompatible with a rejection for anticipation; at best, the reference would seem to suggest (in the § 103 sense) the composition cited by the examiner as the basis of the rejection.[2]

New Ground of Rejection

Under the provisions of 37 CFR § 1.196(b), we make the following new ground of rejection: claim 43 is rejected under 35 U.S.C. § 102(e) as anticipated by Rosner. Claim 43 is directed to a method of stimulating weight loss comprising administering "an acarbose formulation to the patient, wherein such formulation does not include a lipase inhibitor."

[2] We are not suggesting that the examiner should reject the claims as obvious in view of Patel, only that the lack of specificity in the reference would seem to be another problem facing a rejection for anticipation.

Rosner discloses a method "to control weight gain, to provide weight loss and for the prevention or treatment of diabetes." Column 2, lines 11-13. The method comprises ingesting acarbose with meals that contain carbohydrates. See column 1, lines 8-10; claims 1 and 3. Rosner does not teach administering the acarbose in combination with a lipase inhibitor, and therefore the patent is most reasonably interpreted to disclose an acarbose formulation that does not include a lipase inhibitor.

Appellant argues that Rosner does not disclose an acarbose "formulation", as called for in the claim, because "[a]s defined in the specification and recited in the claims, an acarbose formulation is a mixture of acarbose and a sustained release matrix. (Ex. 1, pg. 1, lns 18-20)." Appeal Brief, page 4.[3]

This argument is not persuasive. We have reviewed the entire specification, including the portions cited by Appellant, but have found no definition of the phrase "acarbose formulation" that shows an intention to limit the phrase to formulations containing a sustained release matrix. On the contrary, a acarbose formulation containing a sustained-release matrix is invariably referred to as a "sustained release formulation", or something similar. See, e.g., the title of the application ("Method and composition for controlled release acarbose formulations"); page 2, line 15 ("slow release acarbose formulation"); page 2, line 18 ("sustained release acarbose formulation"); page 6, line 22 ("sustained release formulation of acarbose"); and page 10, line 23 ("acarbose delayed

[3] Appellant also argued that Rosner is not prior art under 35 U.S.C. § 102(a). As explained above (pages 4-5), Appellant is correct, but the reference is prior art under 35 U.S.C. § 102(e).

release formulation"). In addition, on page 3, lines 7-8, the specification discusses an "acarbose formulation" that may be mixed with, and therefore necessarily does not include, a sustained release matrix.

We therefore reject Appellant's strained interpretation of the claim language. The claim reads on administration of acarbose alone and is anticipated by Rosner.

Summary

Neither Bremer nor Patel identically disclose the compositions defined by claims 15-27; we therefore reverse the rejections of these claims. We also reverse the examiner's rejection of claim 43, but enter a new ground of rejection of that claim under the correct statutory provision.

Time Period for Response

This decision contains a new ground of rejection pursuant to 37 CFR § 1.196(b). 37 CFR § 1.196(b) provides that, "A new ground of rejection shall not be considered final for purposes of judicial review."

37 CFR § 1.196(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of proceedings (§ 1.197(c)) as to the rejected claims:

> (1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the application will be remanded to the examiner. . . .
>
> (2) Request that the application be reheard under § 1.197(b) by the Board of Patent Appeals and Interferences upon the same record.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

REVERSED, 37 CFR § 1.196(b)

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